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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,638	10/17/2003	Robert H. Harris	13095B	2598

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EXAMINER

LUKTON, DAVID

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 09/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/688,638	Applicant(s) HARRIS, ROBERT H.	
	Examiner David Lukton	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2005.  
 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.  
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 35, 36, 40-49, 57 and 68-102 is/are pending in the application.  
     4a) Of the above claim(s) 85-102 is/are withdrawn from consideration.  
 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
 6) ☒ Claim(s) 35, 36, 40-49, 57, 68-84 is/are rejected.  
 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Pursuant to the directives of the response filed 7/22/05, claims 35, 36, 40-43, 49 have been amended, claims 37-39, 50-54 cancelled, and claims 73-102 added.

Claims 35, 36, 40-49, 57, 68-102 are now pending.

Claims 35, 36, 40-49, 57, 68-84 are examined in this Office action.

Claims 85-102 are withdrawn from consideration, as they are drawn to a non-elected invention. It is acknowledged that most of the embodiments in these claims were allowed previously (what is now USP 6884910). However, there is nothing to preclude applicants from attempting to expand the scope of claims 85-102 during prosecution, which would require further search and examination. In addition, although claims very similar to claims 85-102 were allowed previously, the examiner is still obligated to conduct a new search of those claims, irrespective of how thorough the search may have been done previously. The examiner thus bears no obligation to rejoin claims 85-102. Nevertheless, in the event that agreement can be reached as to allowable subject matter within the elected invention, the possibility of rejoining claims 85-102 is not precluded. [Applicants should be prepared to submit a terminal disclaimer over U.S. Patent No. 6,884,910, and for that matter, copending application 10/688709].



Applicants' arguments filed 7/22/05 have been considered and found persuasive in part.

- The rejection of claims 35-39 as anticipated by Bialer (USP 6,028,102) is withdrawn.
- The rejection of claim 35 as anticipated by Brennan (USP 6,716,810) is withdrawn.
- The rejection of claim 35 as anticipated by Maccicchini (USP 6,511,963) is withdrawn.
- The rejection of claim 35 as anticipated by Somers (USP 6,034,216) is withdrawn.

. . . . .

The following abbreviations are used hereinbelow:

“EWG” represents an electron-withdrawing group

“EDG” represents an electron-donating group

“EWG/EDG” signifies that a group may be either electron-donating, or electron-withdrawing



The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 35, 36, 40-49, 57, 68-84 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants have shown that the compounds (to which the claims are drawn) can induce analgesia. However, applicants have provided no evidence that the compounds can be used to treat bipolar disorder. Nor have applicants provided any evidence that the compounds can alleviate depression (one of the symptoms of bipolar disorder) or mania (another symptom of bipolar disorder).

As stated in *Ex parte Forman* (230 USPQ 546, 1986) and *In re Wands* (8 USPQ2d 1400, Fed. Cir., 1988) the factors to consider in evaluating the need (or absence of need) for "undue experimentation" are the following: quantity of experimentation necessary, amount of direction or guidance presented, presence or absence of working examples, nature of the invention, state of the prior art, relative skill of those in that art, predictability or unpredictability of the art, and breadth of the claims. At this stage, the most important point is to observe that the "state of the art" is such that the skilled psychiatrist or neurologist would have no reason to expect that compounds which induce analgesia will be effective to treat bipolar disorder.

In addition to the foregoing, the compounds of the invention are known to be effective as anticonvulsants. As noted by Singh (*Psychiatr. Clin. N. Am.* 28, 301, 2005), anticonvulsants are often ineffective in the treatment of bipolar disorder.

In addition to the foregoing, there are no "working examples" which show the skilled artisan how to use the compounds (to which the claims are directed) to treat bipolar disorder.

Thus, (a) the prior art of record supports the conclusion that the skilled artisan would not believe that analgesics will be effective to treat bipolar disorder, (b) Singh (2005) provides reason to doubt that anticonvulsants such as those of the instant claims will be ineffective in the treatment of bipolar disorder, and (c) there are no “working examples” which show the skilled artisan how to use the compounds (to which the claims are directed) to treat bipolar disorder. In accordance with the foregoing, “undue experimentation” would be required to practice the claimed invention.



Claim 82 is objected to because of a typographical error, i.e., the following:

“R<sub>2</sub> s hydrogen”.



Claims 35, 36, 40-49, 57, 68-84 are rejected under 35 U.S.C. § 112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite as to the manifestations of a successful treatment. The first issue is that “bipolar disorder” is really a composite of two different disorders, i.e., mania and depression. Thus, is it sufficient that just one of these is successfully treated, or must both

be successfully treated? Second, the fact is that the manifestations of the disorder are very subjective. Further, even for those who, by an "objective" standard are suffering from the disorder, there will be periods during which no unusual or "aberrant" behavior is exhibited. Further, if a person suffering from the disorder is particularly motivated to hide his (or her) symptoms for a short period of time, he (or she) can do so. The situation with this disorder is very much unlike diseases that affect a physiological symptom. For example, precious few people can control their own blood pressure, and moreover, blood pressure can be objectively assessed. Thus, two different cardiologists investigating the efficacy of an antihypertensive drug, for example, will likely reach the same conclusions. Similarly, one can readily determine, for example, the efficacy (or lack thereof) of an antibacterial agent. In accordance with the foregoing, it is not sufficient for applicants to merely argue that they somehow have "immunity" from a § 112 second paragraph rejection by virtue of the fact that many thousands of patents have issued which contain claims drawn to treatment of a given disease.

Claim 40 recites (last three lines) that " $R_2$  and  $R_3$  are ... substituted by an EWG/EDG". According to one interpretation, however, claim 40 is not properly subgeneric to claim 35, upon which it depends. Claim 35 limits the EWG/EDG (last 4 lines of the claim) to one of 16 possibilities. By contrast, claim 40 can be interpreted to mean that

R<sub>2</sub> and R<sub>3</sub> can be substituted by any EWG/EDG. According to this interpretation, claim 40 is not subgeneric to claim 35. One option would be to cast claim 40 in independent form. The same issue applies with respect to claims 41-43 [see also claim 101].



The following is a quotation of 35 USC §103 which forms the basis for all obviousness rejections set forth in the Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 35, 36, 40-49, 57, 68-84 are rejected under 35 U.S.C. §103 as being unpatentable over Kohn (USP 5,378,729) in view of Post R. M. (*Psychopharmacology* 128 (2) 115-29, 1996) or Yang Y. Y. (*Psychiatry and Clinical Neurosciences* 52 (4) 429-31, 1998) or Keck P. E. (*J. Neuropsychol and Clinical Neurosci* 4, 395-405, 1992).



As indicated previously, Kohn discloses the compounds to which the claims are directed. Kohn also discloses that the compounds are effective anticonvulsants. Kohn does not teach treatment of bipolar disorder. Each of the secondary references discloses that anticonvulsants can be used to treat bipolar disorder.

In response, applicants have pointed to Singh (*Psychiatr. Clin. N. Am.* 28, 301, 2005), who provides an example of an anticonvulsant which is not effective to treat bipolar disease. However, this ground of rejection is imposed from the perspective of one who is unaware of the Singh reference, or who is undeterred by its teaching.

It may be true that there is a case to be made for unpredictability of anticonvulsants generally. But there is also evidence to suggest that many anticonvulsants are effective to treat the disorder in question. The Singh reference does not prove that the compounds of the instant invention will be ineffective, rather the reference provides some reason to doubt that success will be assured. Under the circumstances, it is the position of the examiner that applicants bear the burden of demonstrating that the compounds of Kohn will not be effective to treat bipolar disorder. If persuasive evidence to this effect is supplied, the §103 rejection will be withdrawn. As matters currently stand, however, the rejection is maintained.

Serial No. 10/688,638  
Art Unit 1654

-9-

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached at (571)272-0974. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



DAVID LUKTON  
PATENT EXAMINER  
GROUP 1800